

Civil and Criminal Enforcement by the Department of Justice in the Trump Administration: Business as Usual or New Directions?

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Presented by



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Agenda

What refinements might be made to the Yates Memorandum in the coming months?

Will the risk of corporate executives being fined or prosecuted increase?

What will it take to get cooperation credit in fraud and other white-collar investigations, and must a company be prepared to throw executives under the bus?

The DOJ's latest fraud enforcement directions and theories under the False Claims Act

An update on False Claims Act issues related to cybersecurity, materiality post-*Escobar*, medical necessity, and opioid enforcement

Will there be any easing of enforcement in such areas as the Foreign Corrupt Practices Act, antitrust, and civil rights?

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Refinements to the Yates Memorandum

Background Of Enforcement Developments

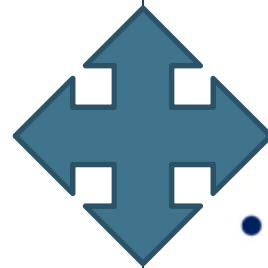
Individual Accountability – What is the Yates Memo?

- First issued on September 9, 2015
- Constitutes new guidelines for Department of Justice attorneys' handling of corporate investigations and prosecutions
- Traditionally, a corporation's cooperation with the federal government's investigation may be factored into how to resolve the case
 - U.S. Attorney's Manual, § 9-28.700 (*The Value of Cooperation*)
- Corporations act through individuals, so investigating the conduct of individuals is the logical means of learning the facts and the extent of corporate misconduct and individual misdeeds
- The Yates Memo sets forth the Department's commitment to seeking individual accountability for corporate wrongdoing

Why The Interest In Individual Accountability?

Purposes Served

- Future illegal activity is deterred.
- Forcing change in corporate behavior.
- The proper parties are held responsible for their actions.



Overall Benefit

- Builds public confidence in the justice system.
- Corporate investigations are handled consistently across sectors further inspiring public confidence.

Yates Memo Guidance

The Six Key Points to Understand

- Eligibility for cooperation credit means that corporations must provide the DOJ all relevant facts about individuals involved in corporate misconduct
- Focus on individuals from start of criminal and civil investigation
- Criminal and civil DOJ attorneys will be in routine communication with each other
- No corporate resolution should provide protection from criminal or civil liability for any culpable individuals
- Corporate cases should not be resolved without a clear plan to resolve related individual cases
- Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based upon factors beyond the ability to pay money to the Government

White Collar Enforcement: DOJ under Sessions

Upcoming changes to the Yates Memorandum

On 10/6/17 at a speech at NYU Law School, DAG Rosenstein highlighted three important forthcoming mandates regarding the DOJ's stance on corporate misconduct and accountability:

1. The department will continue to investigate and prosecute **individual wrongdoers** for corporate misconduct;
2. The federal government will “not use criminal authority unfairly to extract civil payments”; and
3. The Yates Memo will be refined and made more “clear and more concise.”

White Collar Enforcement: DOJ under Sessions

Upcoming changes to the Yates Memorandum

- In order to effectuate these policy changes, DOJ is currently:
 - ramping up training for prosecutors and law enforcement agents regarding corporate fraud, corporate governance, strategies on investigating and prosecuting corporate offenses, and how to build and prosecute cases against culpable individuals;
 - establishing a working group consisting of members from Main Justice, U.S. attorneys' offices, the FBI and other investigative agencies, which will focus on evaluating and monitoring the DOJ's long-term effectiveness in promoting individual accountability and deterring fraud in both civil and criminal cases; and
 - reviewing its high-profile practices and policies concerning corporate monitors, the FCPA pilot program, corporate investigation training programs, and the mandate of the Financial Fraud Enforcement Task Force.

White Collar Enforcement: DOJ under Sessions

Upcoming changes to the Yates Memorandum

DAG Rosenstein also expressed interest in bolstering better public-private cooperation in fighting crime:

- He encouraged the continued use of whistleblowing and self-reporting, specifically as it relates to areas that “are susceptible to detection by good corporate citizens” such as cybercrime, hacking, and financial fraud schemes
- Rosenstein also stressed the importance of reporting wrongdoing or malfeasance to the federal government, even when they may be “in remote places or . . . hidden within complex computer networks” that might otherwise go undiscovered
- As such, Rosenstein noted that DOJ “is working to incentivize, reward, and even partner with companies that demonstrate a commitment to combating corporate fraud.”

White Collar Enforcement: DOJ under Sessions

Upcoming changes to the Yates Memorandum

- DAG Rosenstein spoke on October 25th at the U.S. Chamber Institute for Legal Reform
- He seemed to echo the Yates Memorandum's broader purpose of criticizing heavy corporate fines at the expense of individual accountability and deterrence:
 - “Corporate enforcement and settlement demands must always have a sound basis in the evidence and the law, we should never use the threat of federal enforcement unfairly to extract settlements.”
 - “We should reward prompt reporting of wrongdoing,” and noted that DOJ is currently “evaluating” how to do that.
- DOJ is establishing a “Working Group on Corporate Enforcement and Accountability” to “offer recommendations on promoting individual accountability and corporate cooperation.”

Yates Memo: Going Forward

Issues involving representation and the attorney-client privilege

- Thus, moving forward, it is essential that a practitioner must have a clear sense of precisely who his or her client is
- One can no longer comfortably represent both a corporation through its board and, at the same time, management, if management is a target of a DOJ investigation, whether civil or criminal – and vice versa
- As such, boards may be faced with difficult decisions even earlier in the process as to whether independent counsel will be necessary and whether the Board should stand behind target management
- When a Board forms a special committee to investigate wrongdoing, it may have to make decisions about with whom the findings are shared, which can have significant ramifications for establishing and maintaining attorney-client privilege

Takeaways: Current Status of Yates Memo

- Companies should be aware of and engaging in regular consideration of:
 - In conjunction with the company's board, audit and/or compliance committees, deciding whether and, if so, when independent counsel should be engaged.
 - Determining with whom privileged or sensitive information is shared and how it will be transmitted (*e.g.*, preferably through legal counsel so there is no risk of the communication being interpreted as serving a business, as opposed to legal, purpose);
 - In the event that target executives are being represented independently, considering whether a joint defense agreement is in the interest of the company or whether entering into one might contradict an effort to seek cooperation credit; and
 - Ensuring that sufficient infrastructure and culture exists within a company such that employees are comfortable reporting concerns and sharing information with in-house counsel, so that any potential misconduct can be dealt with before governmental entities are involved.

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New Directions in Fraud Enforcement Under the Sessions DOJ

2016-17 Health Care Fraud Enforcement Activity

DOJ and OIG Not Slowing Down

- Current trends in health care enforcement activity:
 - 501 new health care *qui tam* actions filed in FY2016
 - \$2.6 billion in federal dollar recoveries through health care-related FCA actions
 - OIG expects \$5.6 billion in recoveries in FY2016 through a combination of criminal and civil actions
 - Rise in Medicaid Fraud Control Unit (“MFCU”) actions
 - Recoveries of nearly \$2 billion in FY2016

- Acting Assistant Attorney General Kenneth A. Blanco, May 2017:
 - “Health care fraud is a priority for the Department of Justice. Attorney General Sessions feels very strongly about this. ... The investigation and prosecution of health care fraud will continue; the Department will be vigorous in its pursuit of those who violate the law in this area.”

July 2017 Healthcare Fraud Takedown

- DOJ announces charges against over 400 people for \$1.3 billion in health care fraud (July 13, 2017)
 - “Largest ever health care fraud enforcement action” by the Medicare Fraud Strike Force.
 - Allegedly billed Medicare for \$164 million in fraudulent claims.
 - 295 individuals (including 57 doctors, 162 nurses, and 36 pharmacists) were served with exclusion notices by HHS-OIG for conduct related to opioid diversion and abuse.



Looking Forward: Updates to the OIG Work Plan

- As of June 2017, OIG is releasing monthly updates to the Work Plan
- Several new areas added in the past few months, including:
 - Medicare Part B Claims for Telehealth Services
 - Medicaid Claims for Opioid Treatment Program Services
 - Medicare Payments for Unallowable Home Health Services
 - Medicare Payments for Unallowable Hospice Claims
 - Medicaid Coverage and Reimbursement of Specialty Drugs
 - Medicare Payments for Bariatric Surgery

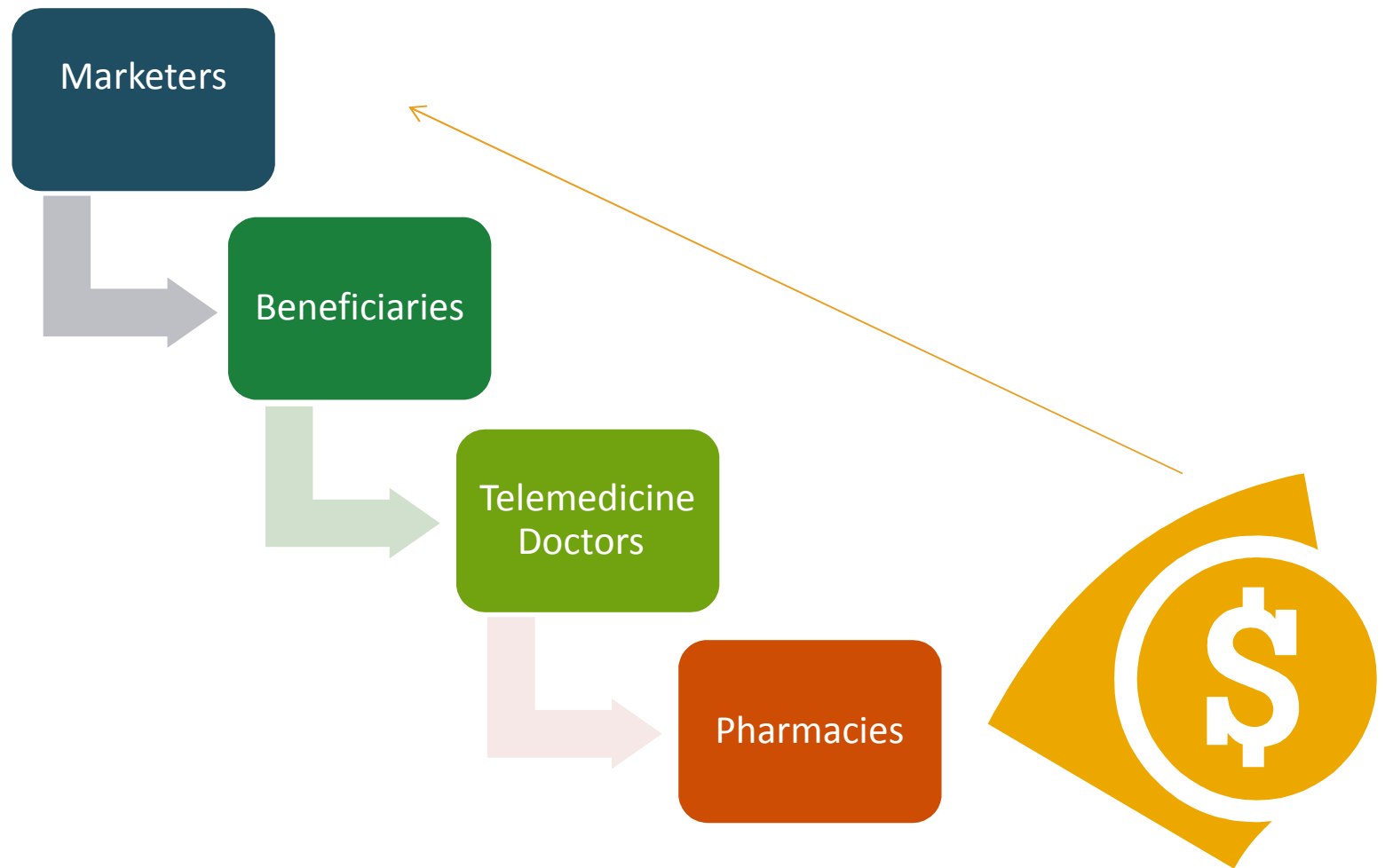
Focusing on: Telemedicine/Telehealth Services

Increased OIG and DOJ Enforcement

- As telehealth becomes more prevalent and states are adapting individual regulatory schemes, the federal enforcement authorities are looking at telemedicine from many angles
- OIG Work Plan reviewing Medicare claims paid for telemedicine services to ensure services are provided at appropriate locations
 - Identified a potential concern with rural originating sites
- Sharp increase in federal criminal enforcement of fraud in telemedicine schemes
 - Unnecessary prescription of compounded drugs is currently the most common target of telemedicine criminal enforcement

Focus on: Telemedicine Fraud Trends

Compound Prescription Drug Scheme



Telemedicine Fraud Trends

Compound Prescription Drug Scheme



- FY 2017 OIG Work plan noted that Part D spending for compounded topical drugs grew by more than 3,400 percent between 2006 and 2015, reaching \$224 million. This growth in spending, combined with an increase in the number of OIG investigative cases involving compounded drugs, suggests the emergence of a fraud risk
- TRICARE paid \$23 million for compounds in 2010. Costs skyrocketed to \$513 million by FY 2014, reaching \$1.7 billion in the first nine months of 2015, when new controls went into effect
- Scheme involves speaker fees, consulting fees, research study fees, etc. as well as telemedicine doctors providing the keys to unlock the doors to lucrative prescriptions for compound medication
- Compounding pharmacies often pre-print the prescriptions and send them to physicians to check a box next to the compounded cream to be used
- Private auto and state workers-compensation insurers are new, emerging targets

Telemedicine Fraud Investigations

Federal Criminal Investigations

- **U.S. v. Jackson et al.** (*M.D. Fl., Docket No. 8:16-cr-264*)
 - Seven Defendants include a physician, a physician assistant, a pharmacist, and several individuals who operated a telemarketing call center
 - Defendants operated a call center that targeted TRICARE beneficiaries for unnecessary compounded medical prescriptions
 - In exchange for kickbacks, clinician Defendants provided signed prescriptions for the targeted TRICARE patients without legitimate provider-patient interactions
 - Defendant pharmacist filled prescriptions and submitted false claims for reimbursement to TRICARE; paid kickbacks to Defendants who operated call center in exchange for the referrals
 - Charged with conspiracy to commit health care fraud and wire fraud, paying and receiving kickbacks, and money laundering
 - Defendants will be serving terms ranging from six months to five years and repayment of restitution up to nearly \$6,000,000 per Defendant

Focus on: Unnecessary Hospice Care Services

Chemed Corp. and Vitas Hospice Services, (W.D. Mo. Oct. 30, 2017)

- Chemed Corporation and Vitas Hospice Services paid \$75 million to resolve allegations that Vitas submitted claims for hospice services to Medicare for patients who were not terminally ill
- Largest ever FCA recovery from a hospice services provider
- Acting Assistant Attorney General Chad A. Readler:
 - “[The] Department will continue to ensure that this valuable benefit is used to assist those who need it, and not as an opportunity to line the pockets of those who seek to abuse it.”

Focus on: Medicare Secondary Payer

Ripe for Enforcement in 2018

- *U.S. ex. rel. Worthy v. Eastern Maine Health Care Systems et al.*, No. 2:2014-cv-00184 (D. Me. 2017)
 - Denied motion to dismiss a FCA action for submitting false and fraudulent claims to Medicare.
 - *Qui tam* action was brought by a former hospital patient account supervisor who alleged that Mercy Hospital systematically removed or omitted accident and injury information in order to be reimbursed for claims, which Medicare otherwise would have withheld payment for under the MSP

- *Negron v. Progressive Cas. Ins. Co.*, No. 14-577, 2016 U.S. Dist. LEXIS 24994 (D. N.J. Mar. 1, 2016)
 - Allowing an insurer’s policyholders to select a “health-first” option, without verifying whether a Medicare or Medicaid plan was implicated, and the subsequent improper submission of claims to the federal government, was sufficiently plead under state and federal FCA
 - The court found the practice to be impermissible, even if the insurer ultimately paid back the government payors, because it allowed the insurer to “receiv[e] an interest free loan from the government on claims they are obligated to pay and were always obligated to pay.”

DOJ Enforcement: Yates Memo in Action

U.S. ex rel. Delaney v. eClinicalWorks, LLC, D. Vt., No. 15-cv-95

- On May 31, 2017, the DOJ settled False Claims Act allegations with electronic health records vendor eClinicalWorks for **\$155 million**
- Settlement resolved allegations that the company and its three founders misrepresented the company's EHR software capabilities
 - ECW falsely obtained certification for its EHR related to HHS's "meaningful use" requirements when it concealed that its software did not comply with the requirements for certification
- Three founders of ECW—its CEO, COO, and CMO—are jointly and severally liable for the enormous settlement
- A developer and two project managers also settled for \$50,000 and \$15,000

DOJ Enforcement: Yates Memo in Action (cont'd)

Norman Regional Health System, No. 5:14-cv-00837 (W.D. Okla., Apr. 11, 2017)

- April 2017 settlement with Norman Regional Health System, along with a former hospital administrator and six physicians
 - *Qui tam* action; government intervened
- Defendants were alleged to have improperly billed Medicare for radiological services performed by radiological practitioner assistants without the required physician “personal” supervision
- Each of the individual defendants were required to pay part of the \$1.6 million settlement

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False Claims Act Updates: Cybersecurity, Materiality Post- *Escobar*, Medical Necessity, and Opioid Enforcement

Cybersecurity and Data Privacy Defense

- *Spokeo v. Robins*, 136 S. Ct. 1540, 578 US ___, 194 L. Ed. 2d 635 (2016).
 - The Supreme Court held that Article III standing requires actual injury in fact, not speculative injury
 - Circuits have divided on whether fear of identity theft qualifies



Materiality Under the FCA Post-*Escobar*

- *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).
 - The Supreme Court recognized “implied false certification” theory of liability, *i.e.*, when a party submits a claim for payment to the government, it impliedly certifies compliance with all conditions of payment, including laws and regulations
 - However, the Court also held that for a contractor to be held liable under the False Claims Act, the government must meet a “demanding” test of materiality.
- *United States ex rel. Harman v. Trinity Industries, Inc.*, No. 15-41172 (5th Cir., Sept. 29, 2017).
 - Government aware of issue that gave rise to the FCA complaint and nevertheless continued to pay on contractors claims.
 - Strong case of no materiality
 - Courts of Appeal differ

Clinical Decision Making as a Basis for FCA Indictments

- DOJ has also recently used criminal statutes to combat the provision of—and submission of claims for—purportedly medically unnecessary treatments
- **Medical Necessity Standard:** Federal health care programs only reimburse providers for items and services that are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” unless another applicable statutory authorization for reimbursement
 - CMS requires that providers certify on claim forms that items or services provided are medically indicated and necessary for the health of the patient
 - Whether an item or service is “medically necessary” for a federal health care program beneficiary is not dependent on a particular provider’s clinical judgment
 - Decision rests with the Secretary of HHS

Criminal Prosecutions: Clinical Decision Making as a Basis for Indictments

- Failure to adhere to medical necessity guidelines may not only constitute a civil FCA violation, but could also be a felony if a provider knowingly and falsely represents the medical necessity of an item or service in the provider's submitted claim
- Federal government's *post hoc* medical necessity determination during an audit or investigation can be unsettling
 - CMS has not delineated precisely what constitutes medical necessity or what documentation is required to substantiate it
 - Yet the provider's judgment/determination may be questioned

Clinical Decision Making as a Basis for Indictments

- Despite this lack of clarity, the federal government has moved to criminalize and has obtained significant convictions in several medical necessity cases
 - In *United States v. Patel* (2012), *United States v. McLean* (2013), and *United States v. Chhibber* (2014), the federal government obtained convictions (all affirmed on appeal) in cases where doctors administered tests or treatments that were later deemed medically unnecessary
- With the increased sophistication of CMS's real-time claims data analysis and use of data mining (*i.e.*, where investigators examine claims for clusters of billing anomalies), it is now easier than ever for government prosecutors to target providers and hospitals reporting higher utilization of certain procedures as compared to peers

The Opioid Crisis At-A-Glance

- Since 1999, the number of prescription opioid overdoses in the U.S. have **quadrupled**, as have the sales of these prescription drugs according to the CDC
- 80% of heroin addiction starts with prescription drug addiction
- In 2014, almost 2 million Americans abused or were dependent upon prescription opioids
- From 2013 to 2015, NJ doctors were paid \$1.67M+ by pharma marketing fentanyl. In the same time period, fentanyl deaths in NJ increased from 42 in 2014 to 417 in 2015.



Recent Enforcement Examples

Federal Civil Settlements and Exclusion

- **CleanSlate Addiction Treatment Centers Settle Allegations of Unlicensed Prescribing and Improper Billing (11/22/16)**
 - \$750,000 civil settlement (FCA and CSA) to resolve allegations that the two companies, which together operate opioid addiction treatment centers in multiple states, improperly prescribed drugs for opioid addiction treatment and improperly billed Medicare.

- **New York Physician Agrees to Another Voluntary Exclusion (5/17/17)**
 - In connection with the resolution of his FCA liability, Dr. Michael Esposito agreed to be excluded again from participation in all Federal health care programs for 15 years.
 - OIG's investigation revealed that despite previously having been excluded for five years beginning December 2016, he forged another physician's signature on prescriptions, including opioids, in order to obtain medications for himself and another person.
 - Dr. Esposito also presented claims for payment to Medicare for services that he furnished, ordered, and prescribed to Medicare beneficiaries while excluded.

Insys Therapeutics, Inc.

U.S. v. Babich et al., Crim. No. 16-10343 (D. Mass. Dec. 6, 2016 – superseding indictment October 26, 2017)

- Seven former executives are accused of bribing doctors to prescribe a spray version of fentanyl, Subsys, intended as a last resort to treat breakthrough cancer pain, often to patients without cancer.
- Insys managers allegedly paid medical practitioners to speak at sham events where their primary goal was to prescribe Subsys. If the practitioners didn't write enough prescriptions, Insys would reduce their number of paid speaking events. Set up a "reimbursement unit," allegedly to obtain prior authorizations from insurers and PBMs.

FENTANYL

Known as Subsys, Duragesic, and Abstral.

Fentanyl is a strong prescription pain medicine that contains an opioid (narcotic). It is used to manage breakthrough pain in cancer patients.

WARNING:

- May be habit forming.

Galena Biopharma, Inc. Settlement

District of New Jersey, Sept. 8, 2017

- More than \$7.55 million civil False Claims Act settlement to resolve allegations that Galena paid physicians kickbacks in exchange for prescribing high volumes of Fentanyl-based drug, Abstral.
- Alleged improper payments for “advisory board” participation and incentive agreements.
- Allegedly involved 2 physicians who were convicted of running a “pill mill” who were sentenced to 20+ years in prison in S.D. Alabama.



Recent Enforcement Examples

FBI Seizure

■ Alpha Bay (July 2017)

- Alpha Bay is the largest darknet marketplace for illegal drugs, particularly heroin and fentanyl. Sales have been linked to multiple overdose death in the U.S.
- Alpha Bay had operated for more than two years and had transactions exceeding \$1 billion. Joint action by FBI, DEA and European authorities
- The site's creator and administrator were arrested and their assets were seized, as well as millions of dollars in cryptocurrency.



Opioid Fraud and Abuse Detection Unit

August 2, 2017 DOJ Update

- DOJ pilot to utilize data to help combat opioid fraud and abuse
- Focus specifically on opioid-related health care fraud using data to identify and prosecute individuals that are contributing to opioid overuse
- Specifically targeting “pill mill” schemes and pharmacies that unlawfully dispense or divert prescription opioids for abuse
- Like other initiatives, rooted in data mining

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Easing of Enforcement: Foreign Corrupt Practices Act

What is the FCPA?

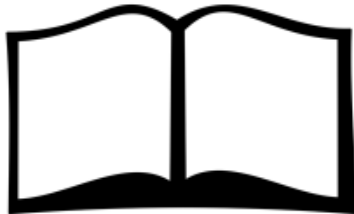
Prohibits individuals and businesses from knowingly making payments to foreign officials in order to obtain or retain business or secure an improper advantage

Key Elements – It is unlawful for

- a U.S. person, U.S. company, or any other person in the U.S.
- with corrupt intent, to offer, pay, promise to pay, or authorize payment of, directly or indirectly, anything of value
- to a “foreign official,” foreign political party (or official thereof), or any candidate for foreign political office (each a “covered official”), or any person while “knowing” that all or a portion of the payment or thing of value will be offered, given, or promised directly or indirectly to a covered official
- for the purpose of influencing any official act or decision, inducing any act or omission in violation of a lawful official duty, or securing an improper advantage
- in order to assist in obtaining, retaining, or directing business to any person

FCPA Books & Records Provisions

- Civil enforcement of accounting standards and internal controls
- Civil injunctive authority, fines & disgorgement of profits



What is likely ahead for FCPA enforcement?

- FCPA Unit has run a pilot program since April 2016 to encourage self-reporting
- Securities and Exchange Commission and Commodity Futures Trading Commission are following suit with their own self-reporting and cooperation policies with the promise of speedier resolutions combined with decreased penalties.
- Other DOJ sections/units to follow suit?
- New head of SEC-FCPA Unit appointed just this week

Foreign Corrupt Practices Act & Healthcare

- A major new announcement DOJ in July 2017 by acting Criminal Fraud Chief Sandra Moser: coordination between the DOJ's Healthcare Fraud Unit's Corporate Strike Force and FCPA prosecutors.
 - Their mission is to “investigate and prosecute matters relating to health care bribery schemes, both domestic and abroad.”
 - Constant them from Sessions and other DOJ leadership: “We will continue to strongly enforce the FCPA and other anti-corruption laws”

- Slowdown in both healthcare fraud and FCPA cases brought by Main Justice in the first half of 2017, the DOJ is stepping up its enforcement efforts.
- Sources: Cases are in the works – increase hiring in FCPA unit
- Overlooked: FCPA unit has had three jury trials this spring and summer – most trials and successes in a year ever
- DOJ emphasis on voluntary compliance & self disclosure
- DOJ continued emphasis on holding individuals accountable for corporate misconduct

More from Acting Criminal Fraud Chief Moser

She has urged companies to **“empower”** their compliance executives now, rather than forcing them to “sit before the Department and defend a program that they fought to make better and were denied the resources or backing to see through.”

Looking forward, companies would be well served by Moser’s warning that they need to **“invest in compliance now rather than using that would-be investment to pay a criminal fine down the road.”**

Questions?



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Thank You.